

IN THE UNITED STATES DISTRICT COURT  
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/ FENFLURAMINE/DEXFENFLURAMINE) PRODUCTS LIABILITY LITIGATION	)	MDL NO. 1203
_____	)	
THIS DOCUMENT RELATES TO:	)	
	)	
SHEILA BROWN, et al.	)	
	)	CIVIL ACTION NO. 99-20593
v.	)	
	)	
AMERICAN HOME PRODUCTS CORPORATION	)	2:16 MD 1203

**MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO.**

Bartle, C.J.

July 2, 2010

Barbara Mauch ("Ms. Mauch" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,<sup>1</sup> seeks benefits from the AHP Settlement Trust ("Trust"). Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").<sup>2</sup>

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1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1  
(continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In October, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Charles M. Rasmussen, M.D. Based on an echocardiogram dated September 11, 2001, Dr. Rasmussen attested in Part II of Ms. Mauch's Green Form that she suffered from moderate mitral regurgitation, pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%.<sup>3</sup>

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2. (...continued)

describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

3. In addition, Dr. Rasmussen attested that claimant had moderate aortic regurgitation, mild or greater aortic

(continued...)

Based on such findings, claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$476,887.<sup>4</sup>

Dr. Rasmussen also attested in claimant's Green Form that Ms. Mauch did not suffer from mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d). As the Trust does not contest Ms. Mauch's entitlement to Level II benefits, the only issue before us is whether claimant is entitled to payment on Matrix A-1 or Matrix B-1.

In October, 2003, the Trust forwarded the claim for review by Andrew D. Sumner, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Sumner concluded that there was no reasonable medical basis for Dr. Rasmussen's finding that claimant did not have mitral annular calcification. In support of this conclusion, Dr. Sumner explained that "[m]itral annular

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3. (...continued)  
regurgitation confirmed by echocardiography prior to Pondimin® and/or Redux™ use, and New York Heart Association Functional Class I symptoms. These conditions, however, are not at issue in this claim.

4. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). Pulmonary hypertension secondary to moderate or greater mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction are three of the five complicating factors needed to qualify for a Level II claim.

clarification is visualized on the parasternal short and long axis (predominantly involving posterior portion of the annulus)."

Based on Dr. Sumner's finding that claimant had mitral annular calcification, the Trust issued a post-audit determination that Ms. Mauch was entitled only to Matrix B-1, Level II benefits.<sup>5</sup> Pursuant to the Rules for the Audit of Matrix Compensation Claims ("Audit Rules"), claimant contested this adverse determination.<sup>6</sup> In contest, claimant argued that her mitral annular calcification "is minimal and of no clinical significance" and "does not account for [her] severe mitral regurgitation." In support, she submitted an affidavit from Wilbert S. Aronow, M.D., F.A.C.C. In his affidavit, Dr. Aronow stated, in relevant part:

4. Based on my review, Barbara Mauch only has a small amount of mitral annular calcium. She also has severe mitral regurgitation.

5. Mitral annular calcium is commonly seen in older individuals.

6. In my opinion, Barbara Mauch's very small amount of mitral annular calcium that is

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5. In its post-audit determination letter, the Trust stated that Ms. Mauch's claim was payable on Matrix B-1 due to "mitral valve prolapse and mitral valve lesions of a type associated with bacterial endocarditis." The Trust subsequently issued an amended post-audit determination letter correcting this error.

6. Claims placed into audit on or before December 1, 2002 are governed by the Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit, as approved in Pretrial Order ("PTO") No. 2457 (May 31, 2002). Claims placed into audit after December 1, 2002 are governed by the Audit Rules, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Rules contained in PTO No. 2807 apply to Ms. Mauch's claim.

seen on the echocardiogram does not account for either moderate or severe regurgitation. Therefore, her regurgitation must be considered to be caused by some other entity.

Accordingly, in claimant's view, "[m]itral annular calcifications that are not causing the moderate or severe regurgitation should not be utilized to substantially reduce the benefits of a claimant."

The Trust then issued a final post-audit determination, again determining that Ms. Mauch was entitled only to Matrix B-1, Level II benefits. Claimant disputed this final determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2807, Audit Rule 18(c). The Trust then applied to the court for issuance of an Order to show cause why Ms. Mauch's claim should be paid. On January 3, 2005, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 4305 (Jan. 3, 2005).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on May 31, 2005. The Show Cause Record is now before the court for final determination. See Audit Rule 35.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a

reasonable medical basis for the attesting physician's finding that she did not have mitral annular calcification. See id. Rule 24. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. Rule 38(a). If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id. Rule 38(b).

In support of her claim, Ms. Mauch argues that it is not appropriate to reduce her claim to Matrix B-1 based on mitral annular calcification because the amount of mitral annular calcification present on her echocardiogram had "no effect on the valvular dysfunction being compensated for...." (Emphasis in original.)<sup>7</sup> Claimant further suggests that other reduction factors for mitral valve claims "require present effect on the valvular dysfunction in order to be considered a reduction factor." (Emphasis in original.)<sup>8</sup>

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7. In support, claimant submits an article from the American Heart Journal and the affidavit from Dr. Aronow that she submitted in contest.

8. In addition, claimant asserts that applying the Settlement Agreement as written "discriminates against older people since minimal amounts of mitral annular calcification are commonly found in the older population." Age, however, was considered by the parties in determining the conditions that would reduce the amount of Matrix Benefits due to a claimant. See, e.g., Settlement Agreement § IV.B.2.d.(2)(c)i)c) (reduction factor of  
(continued...)

In response, the Trust argues that, under the Settlement Agreement, any amount of mitral annular calcification reduces a mitral valve claim to Matrix B-1, regardless of whether the mitral annular calcification caused the regurgitation at issue.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, and of crucial importance, claimant does not refute Dr. Sumner's conclusion that claimant's echocardiogram demonstrated the presence of mitral annular calcification. Indeed, claimant's expert in contest, Dr. Aronow, confirmed Dr. Sumner's conclusion that Ms. Mauch had mitral annular calcification. Under the Settlement Agreement, the presence of mitral annular calcification requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)ii)d).<sup>9</sup> On this basis alone, claimant has failed to meet her burden of demonstrating that there is a reasonable medical basis for her claim.

In addition, we reject claimant's argument that mitral annular calcification must be clinically significant to justify a reduction in Matrix Benefits. As noted above, the Settlement

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8. (...continued)  
aortic sclerosis applied to individuals sixty (60) years of age or older). As the Settlement Agreement does not provide an age restriction for mitral annular calcification, we decline claimant's request to draft such a restriction into the Settlement Agreement.

9. For this reason as well, we reject claimant's argument that the reduction factor of mitral annular calcification requires a "present effect" on the regurgitation at issue.

Agreement specifically provides that a claimant will receive reduced Matrix Benefits for a mitral valve claim if he or she is diagnosed by echocardiogram with mitral annular calcification. See id. Although claimant relies on Dr. Aronow's opinion that her mitral annular calcification was not clinically significant, unlike some of the other factors that reduce a claim to Matrix B-1, the presence of mitral annular calcification, regardless of the amount, requires the payment of reduced Matrix Benefits. See, e.g., id. § IV.B.2.d.(2)(c)i)d) (requiring "aortic root dilatation > 5.0 cm" for application of reduction factor).

Finally, claimant's reliance on Dr. Aronow's opinion that the presence of mitral annular calcification was not the medical cause of Ms. Mauch's mitral regurgitation is misplaced. Causation is not at issue in resolving Ms. Mauch's claim for Matrix Benefits. Rather, claimant is required to show that she meets the objective criteria set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [I]ndividual issues relating to causation, injury and damage also disappear because the settlement's objective criteria



provide for an objective scheme of compensation.

Id. at 97. If claimants are not required to demonstrate causation, the converse also is true; namely, in applying the terms of the Settlement Agreement, the Trust does not need to establish that a reduction factor caused the regurgitation at issue. The Settlement Agreement clearly and unequivocally requires a claim based on damage to the mitral valve to be reduced to Matrix B-1 if any amount of mitral annular calcification is present. We must apply the Settlement Agreement as written. Accordingly, Dr. Aronow's opinion that claimant's mitral annular calcification was not the cause of her mitral regurgitation is irrelevant.

For the foregoing reasons, we conclude that claimant has not met her burden of proving that there is a reasonable medical basis for finding that she did not have mitral annular calcification. Therefore, we will affirm the Trust's denial of Ms. Mauch's claim for Matrix A-1 Benefits.